



APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/488,180	06/07/95	CARNEY	W 40441-CY/JPW
EXAMINER			

18M1/0107

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SCHEINER, T
ART UNIT

1806

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DATE MAILED: 01/07/98

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on Oct 6, 97 & Oct 20, 97
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- ☒ Claim(s) 13-24 is/are pending in the application.
- ☒ Of the above, claim(s) 16-24 is/are withdrawn from consideration.
- ☒ Claim(s) 13-15 is/are allowed.
- ☐ Claim(s) 13-15 is/are rejected.
- ☐ Claim(s) is/are objected to.
- ☐ Claim(s) are subject to restriction or election requirement.

#### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

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### DETAILED ACTION

Claims 19-24 have been entered by the amendment filed October 6, 1997. Claims 13-24 are pending in the application.

The rejection of claims 16-18 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicants' assurances for the deposit of biological material.

The rejection of claims 16-18 under 35 U.S.C. 102 (a) as anticipated by McKenzie *et al.* (Oncogene, vol. 4, no. 5, pp. 543-548, May 1989) is withdrawn in view of the explicit disclosure of antibodies TA1, OD3 and NB3 in parent application serial no. 07/182,501 (filed April 18, 1988).

The rejection of claims 13 and 15 under 35 U.S.C. 102 (b) as anticipated by Drebin *et al.* (Nature, vol. 312, no. 5994, pp. 545-548, December 1984) is withdrawn in view of the declaration of Arthur Bruskin, filed October 20, 1997, under 37 C.F.R. 1.132.

The rejection of claim 14 under 35 U.S.C. 103 as unpatentable over Drebin *et al.* (Nature, vol. 312, no. 5994, pp. 545-548, December 1984) is withdrawn in view of the declaration of Arthur Bruskin, filed October 20, 1997, under 37 C.F.R. 1.132.

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The rejection of claims 16-18 under 35 U.S.C. 103 as unpatentable over Masuko *et al.* (Jpn. J. Cancer Res., vol. 80, pp. 10-14, January 1989) is withdrawn in view of the explicit disclosure of antibodies TA1, OD3 and NB3 in parent application serial no. 07/182,501 (filed April 18, 1988).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 13 and 15 are rejected under 35 U.S.C. 102(a) as being anticipated by McKenzie *et al.* (Oncogene, vol. 4, no. 5, pp. 543-548, May 1989) for reasons of record.

Applicants urge that the subject matter of these claims is supported in parent application serial no. 07/182,501 (filed April 18, 1988) which discloses monoclonal antibodies TA1, OD3 and NB3. However, the fact that these antibodies were ultimately found to bind to the extracellular domain of the human *neu* gene product does not support the concept of a genus of antibodies specific for the extracellular domain. The recognition of a class of antibodies binding the extracellular domain is not evident in parent application serial no. 07/182,501. **Please note that parent application serial no. 07/182,501 has been unavailable to the examiner for review for some time; if applicants can provide official photocopies of any language from the parent**

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**application supporting the general recognition of a class of antibodies binding the extracellular domain, it would be appreciated, and this and the following rejections would be obviated.**

Claims 13 and 15 are rejected under 35 U.S.C. 102(a) as being anticipated by Masuko *et al.* (Jpn. J. Cancer Res., vol. 80, pp. 10-14, January 1989) for reasons of record.

Applicants urge that the subject matter of these claims is supported in parent application serial no. 07/182,501 (filed April 18, 1988) which discloses monoclonal antibodies TA1, OD3 and NB3. However, the fact that these antibodies were ultimately found to bind to the extracellular domain of the human *neu* gene product does not support the concept of a genus of antibodies specific for the extracellular domain. The recognition of a class of antibodies binding the extracellular domain is not evident in parent application serial no. 07/182,501.

***Claim Rejections - 35 USC § 103***

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over McKenzie *et al.* (Oncogene, vol. 4, no. 5, pp. 543-548, May 1989) for reasons of record.

Applicants urge that the subject matter of these claims is supported in parent application serial no. 07/182,501 (filed April 18, 1988) which discloses monoclonal antibodies TA1, OD3 and NB3. However, the fact that these antibodies were ultimately found to bind to the extracellular domain of the human *neu* gene product does not support the concept of a genus of antibodies

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specific for the extracellular domain. The recognition of a class of antibodies binding the extracellular domain is not evident in parent application serial no. 07/182,501.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Masuko *et al.* (Jpn. J. Cancer Res., vol. 80, pp. 10-14, January 1989) for reasons of record.

Applicants urge that the subject matter of these claims is supported in parent application serial no. 07/182,501 (filed April 18, 1988) which discloses monoclonal antibodies TA1, OD3 and NB3. However, the fact that these antibodies were ultimately found to bind to the extracellular domain of the human *neu* gene product does not support the concept of a genus of antibodies specific for the extracellular domain. The recognition of a class of antibodies binding the extracellular domain is not evident in parent application serial no. 07/182,501.

### ***Conclusion***

**Claims 16-24 are allowable.**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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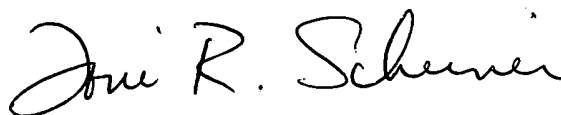
the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Toni R. Scheiner whose telephone number is (703) 308-3983. The examiner can normally be reached Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, , can be reached on (703) . The fax phone number for this Group is (703) .

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

12/22/97



TONI R. SCHEINER  
PRIMARY EXAMINER  
GROUP 1800